JUL - 2 2009

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

MILI (Minimally Invasive Lumbar Implant) System
June 5, 2009

COMPANY:	Aesculap Implant Systems, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 3005673311
CONTACT:	Lisa M. Boyle 800-258-1946 (phone) 610-791-6882 (fax)
TRADE NAME:	MILI
COMMON NAME:	Minimally Invasive Lumbar Implant (MILI) System
CLASSIFICATION NAME:	Non-cervical, Pedicle System (MNH, MNI, NKB)
REGULATION NUMBER:	888.3070

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems (AIS), Inc., believes that the MILI System is substantially equivalent to the S4 Lumbar Spinal System (also known as Revolution) (K032219), and the Ascend Spinal Fixation System with the Shadow Spinal System (K013196).

DEVICE DESCRIPTION

The Aesculap Implant Systems (AIS) MILI System is a minimally invasive posterior plating system for the thoracolumbar spine. This system is intended for posterior, non-cervical pedicle fixation. The AIS MILI System consists of plates and cannulated screws. The components are available in a variety of lengths in order to accommodate patient anatomy. The AIS MILI System is manufactured from Titanium/Titanium Alloy and will be provided non-sterile.

INDICATIONS FOR USE

The MILI System is intended for posterior, non-cervical pedicle fixation of the spine. It is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of one or more of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolithesis (Grade I/II) with objective evidence of neurological impairment, fracture,

dislocation, scoliosis (one level), kyphosis, spinal tumor, failed previous fusion (pseudarthrosis),

The MILI System, when used as a pedicle screw fixation system, is indicated for use in patients: a) who are receiving fusion using autogenous graft only; b) who are having the device fixed or attached to the thoracolumbar or sacral spine; and c) who are having the device removed after the development of a solid fusion mass.

The MILI System is indicated only for one-level or adjacent two-level procedures.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The AIS MILI System is considered substantially equivalent to other legally marketed predicate systems. Biomechanical testing of the subject device was found to be similar in performance to previously cleared spinal systems with similar indications.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the "Spinal System 510(k)s" was completed where relevant. Mechanic testing demonstrates that Aesculap's MILI System is safe and effective comparable to other predicate systems currently on the market.

In addition, cadaver testing confirms that the MILI System can successfully be implanted according to the specified minimally invasive surgical technique.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2009

Aesculap Implant Systems, Inc.
% Ms. Lisa M. Boyle
Senior Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K083004
Trade/Device Name: Minimally Invasive Lumbar Implant (MILI) System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: Class III
Product Code: NKB, MNI, and MNH
Dated: June 3, 2009
Received: June 4, 2009

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 1 of 1

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K083004

Device Name: MILI (Minimally Invasive Lumbar Implant) System

Indications for Use:

The MILI System is intended for posterior, non-cervical pedicle fixation of the spine. It is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of one or more of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolithesis (Grade I/II) with objective evidence of neurological impairment, fracture, dislocation, scoliosis (one level), kyphosis, spinal tumor, failed previous fusion (pseudarthrosis),

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The MILI System is indicated only for one-level or adjacent two-level procedures.

Prescription Use X and/or Over-the-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(EXT for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083004